Site-Specific Risk Assessments

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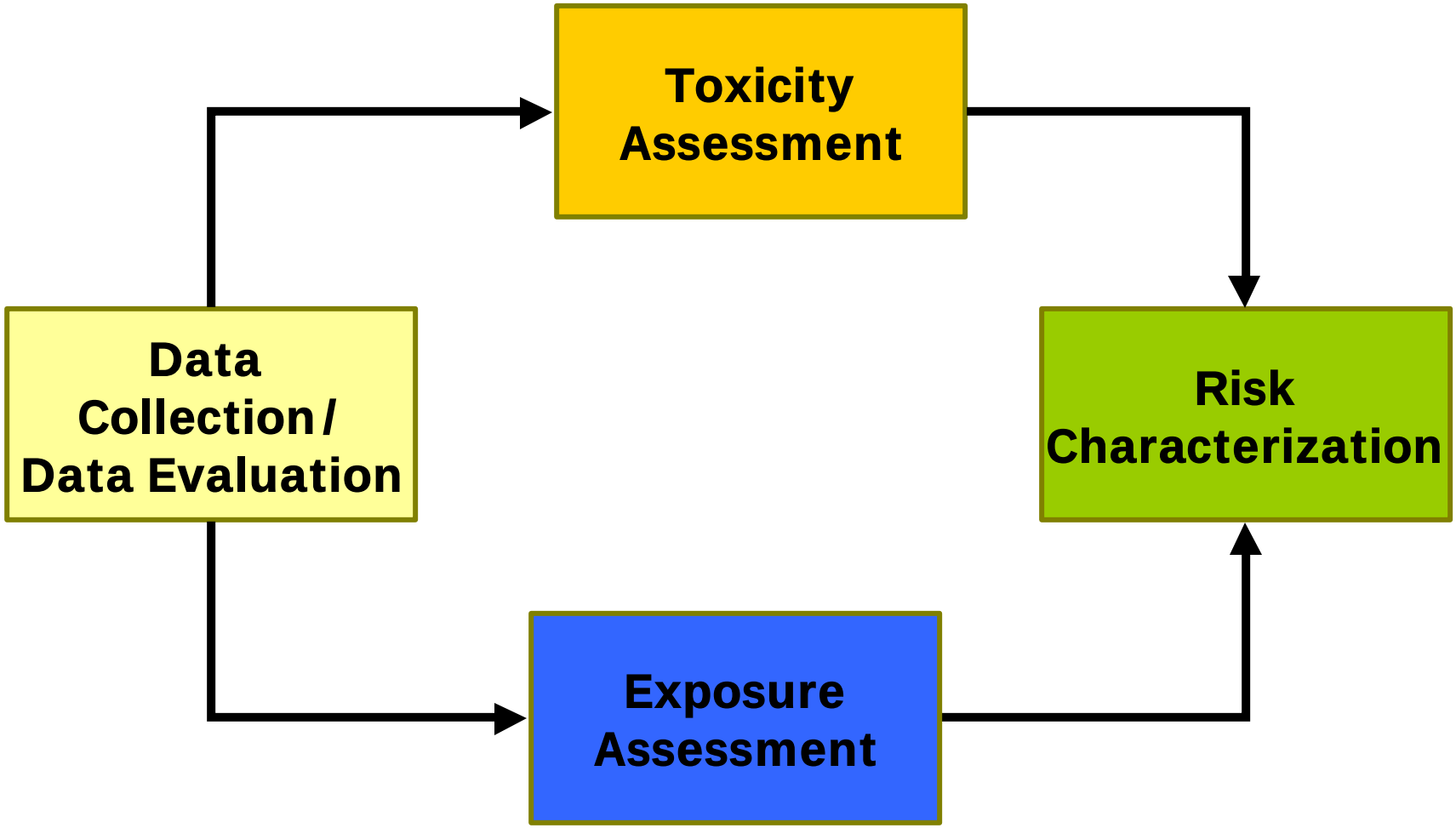
NEWFIELDS
25 Feb 2003

Steps in Risk Assessment Process



Baseline Risk Assessment Generic Equation

$$\text{Risk} = \text{Concentration} * \frac{(IR * EF * ED)}{BW*AT} * TF$$

Carcinogenic Risk & Hazard Index:

Current & Future RME (95th) and CTE (50th percentile)

Chemical Concentration Data Collection & Evaluation:

Sampling, DQO/ DQA, Background Analysis, COCs

Exposure Assessment:

Intake Rate, Bioavailability; Exposure Point Concentration

Toxicity Assessment:

Carcinogenic Slope Factor or Reference Dose

Toxicity Assessment

NON-CARCINOGENIC RESPONSE

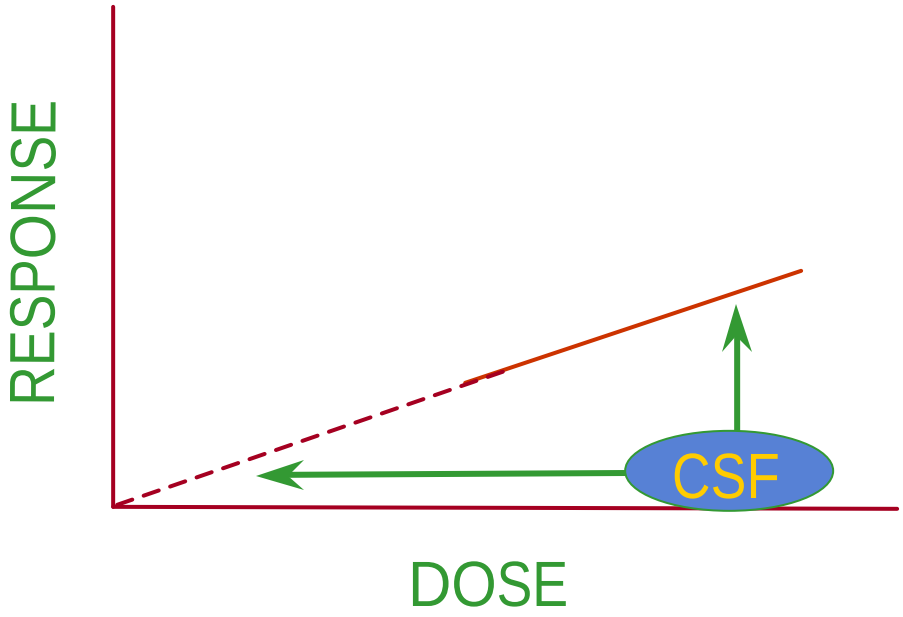
Reference Dose (RfD): An estimate of a daily exposure level for the human population, including sensitive subpopulations, that is likely to be without deleterious effects during a lifetime.

CARCINOGENIC EFFECTS

Slope Factor (SF): The plausible upper bound probability of excess lifetime risk - expressed in units of risk per mg/kg/day

Toxicity Assessment

CARCINOGENIC RESPONSE



The carcinogenic potency is determined by the slope of the line:
The steeper the slope, the more potent the carcinogen

Toxicity Assessment

Dose - Response Relationships

(Non-cancer response)

RfD = NOAEL or LOAEL/(UFs * MF)

RfD
Reference Dose

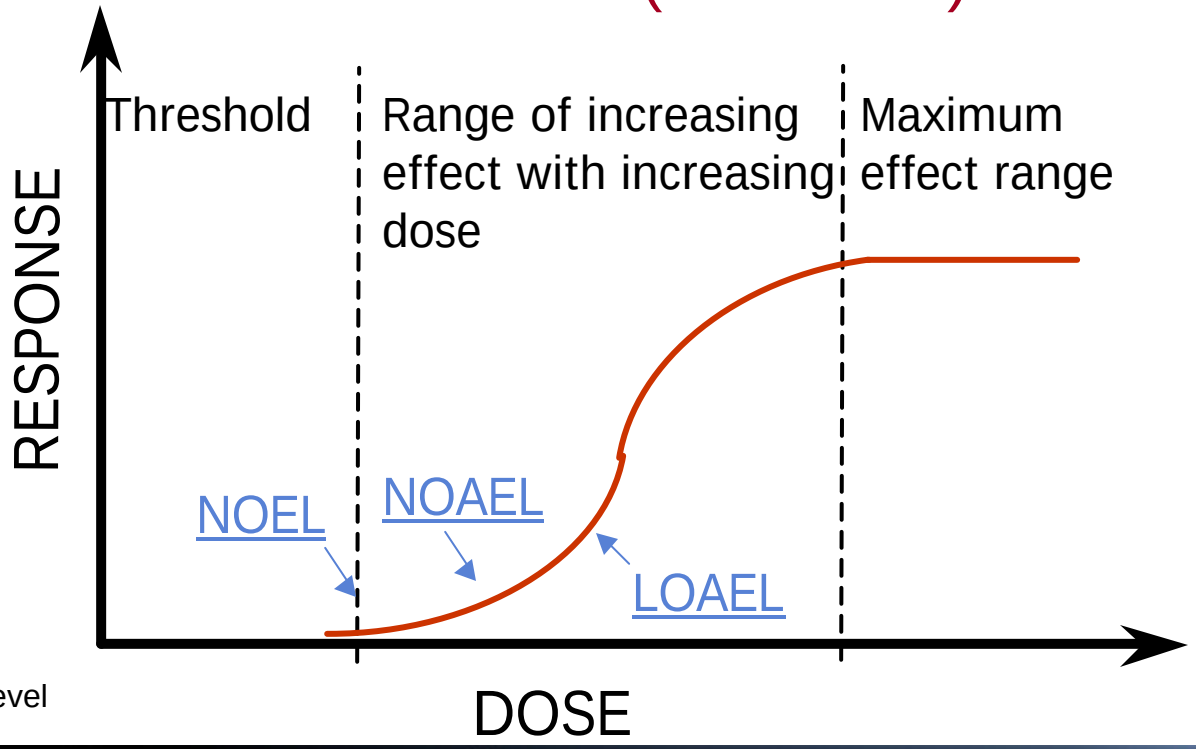
UF
Uncertainty Factor

MF
Modifying Factor

NOEL
No Observed Effect Level

NOAEL
No Observed Adverse Effect Level

LOAEL
Lowest Observed Adverse Effect Level



Sources of Toxicity Information

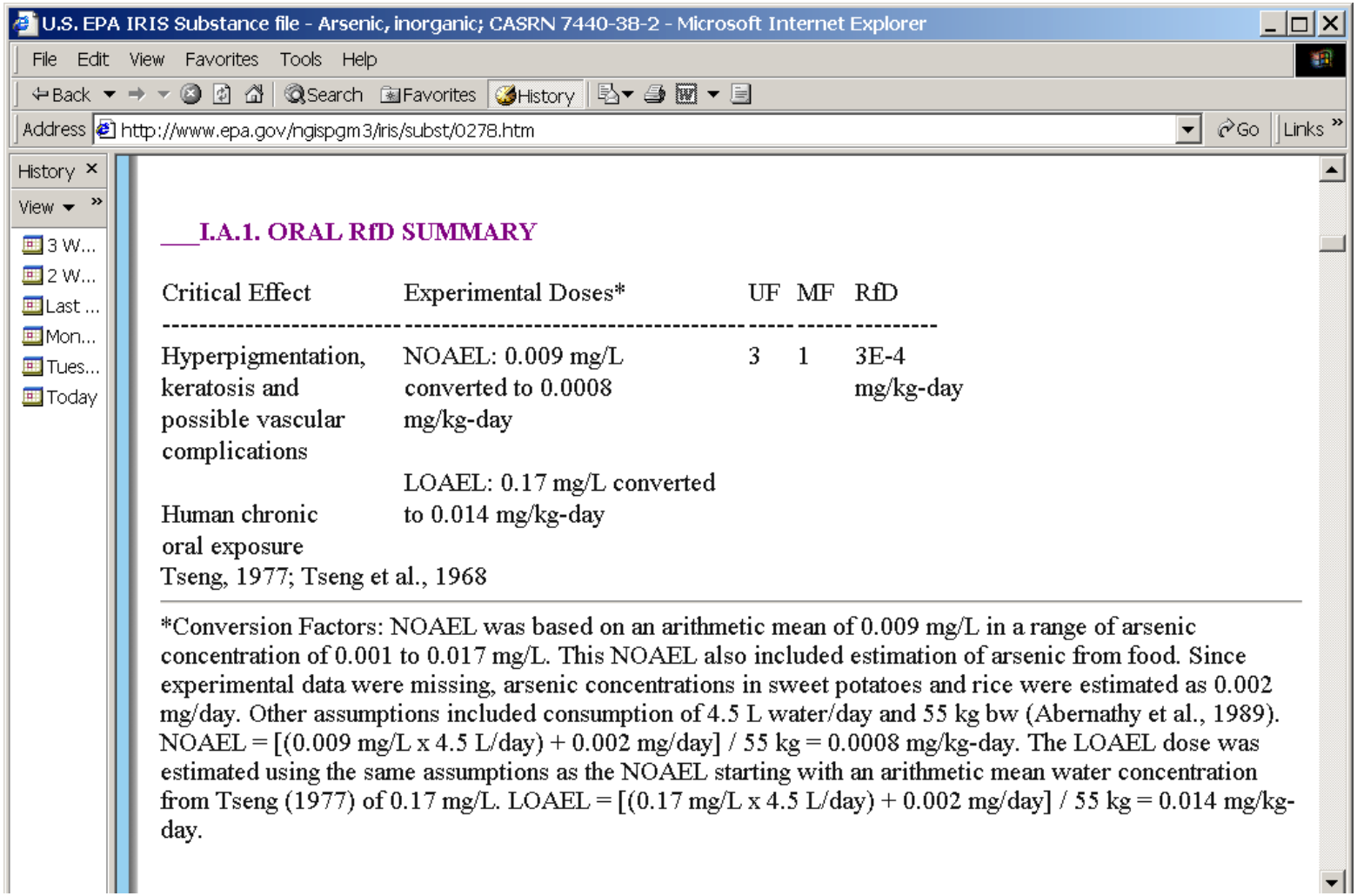
IRIS - Integrated Risk Information System

- http://www.epa.gov/iriswebp/iris/index.html

HEAST - Health Effects Assessment Summary Tables

- Only hardcopies available

Sources of Toxicity Data

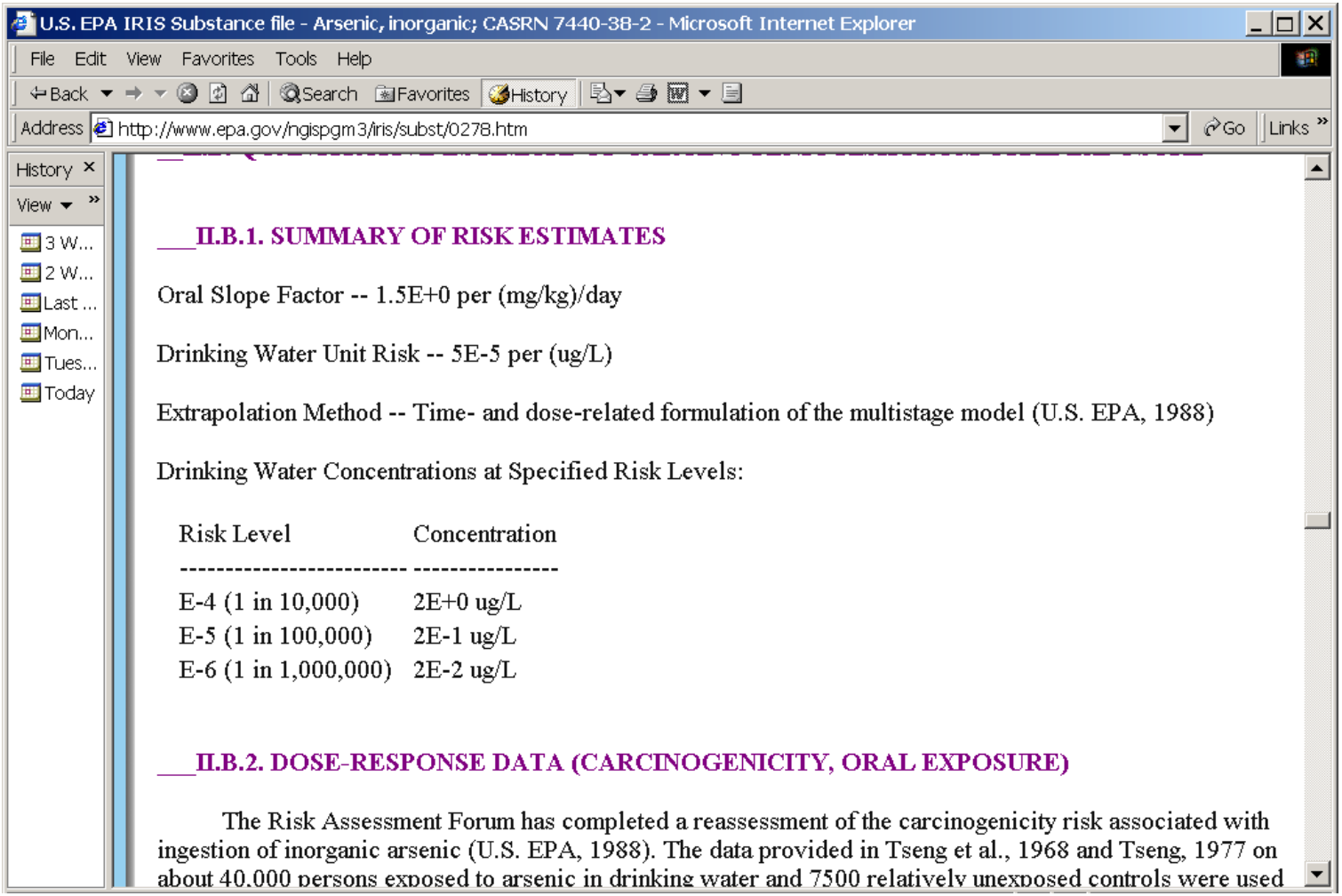


I.A.1. ORAL RfD SUMMARY

Critical Effect	Experimental Doses*	UF	MF	RfD
Hyperpigmentation, keratosis and possible vascular complications	NOAEL: 0.009 mg/L converted to 0.0008 mg/kg-day	3	1	3E-4 mg/kg-day
Human chronic oral exposure Tseng, 1977; Tseng et al., 1968	LOAEL: 0.17 mg/L converted to 0.014 mg/kg-day			

*Conversion Factors: NOAEL was based on an arithmetic mean of 0.009 mg/L in a range of arsenic concentration of 0.001 to 0.017 mg/L. This NOAEL also included estimation of arsenic from food. Since experimental data were missing, arsenic concentrations in sweet potatoes and rice were estimated as 0.002 mg/day. Other assumptions included consumption of 4.5 L water/day and 55 kg bw (Abernathy et al., 1989). NOAEL = [(0.009 mg/L x 4.5 L/day) + 0.002 mg/day] / 55 kg = 0.0008 mg/kg-day. The LOAEL dose was estimated using the same assumptions as the NOAEL starting with an arithmetic mean water concentration from Tseng (1977) of 0.17 mg/L. LOAEL = [(0.17 mg/L x 4.5 L/day) + 0.002 mg/day] / 55 kg = 0.014 mg/kg-day.

Sources of Toxicity Data



Exposure Assessment

Estimates the way people come into contact with substances and how much they could take into their bodies

- Who - people exposed
- What - groundwater, constituents, etc.
- When - daily, x times/year for 30 years
- Where - exposure domain, site-wide
- How - ingestion, inhalation
- How Much - mg/kg/day

Past or Future

Past Exposures – ATSDR performs Public Health Assessments at all CERCLA sites

- PHAs focus on past exposure
- Existing health problems

Future Exposures – we are performing CERCLA–type risk assessments

- RAs focus on potential future exposure
- Potential health problems

Who Do We Evaluate?

Maximum Exposed Individual (MEI)

Average Exposure (CT)

Reasonable Maximum Exposure (RME)

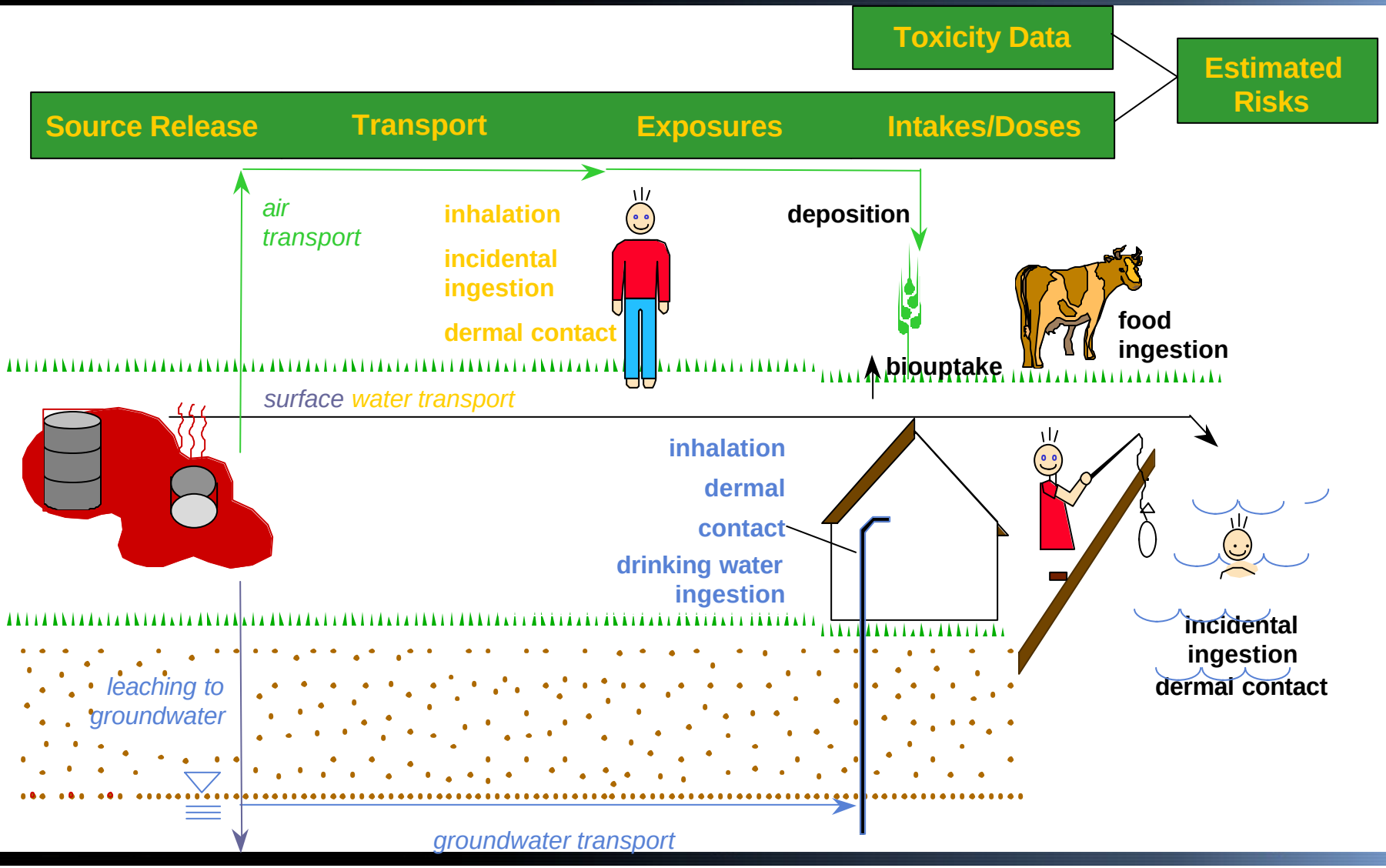
The highest exposure that is reasonably expected to occur at a site.

(To estimate exposure that is well above the average case but is still within the range of possible exposures.)

Site Conceptual Model

- Identifies:
  - Contamination sources
  - Chemical types and concentrations
  - Potentially contaminated media
  - Potential pathways
  - Potential receptors

Develop Site Conceptual Model



RAGS D Table 1

TABLE 1
SELECTION OF EXPOSURE PATHWAYS
SITE NAME

Scenario Timeframe	Medium	Exposure Medium	Exposure Point	Receptor Population	Receptor Age	Exposure Route	On-Site/ Off-Site	Type of Analysis	Rationale for Selection or Exclusion of Exposure Pathway

Quantitative
Qualitative
Not evaluated

This table presents the information compiled during development of the Site Conceptual Model

Define Exposure Unit

Exposure Domain

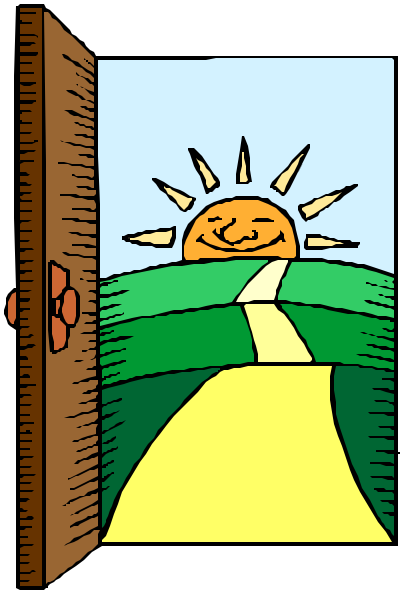
- Where are people likely to be exposed?
  - whole site
  - portions of site
- Consider land use
  - current
  - future

Exposure domain is used to calculate exposure concentrations

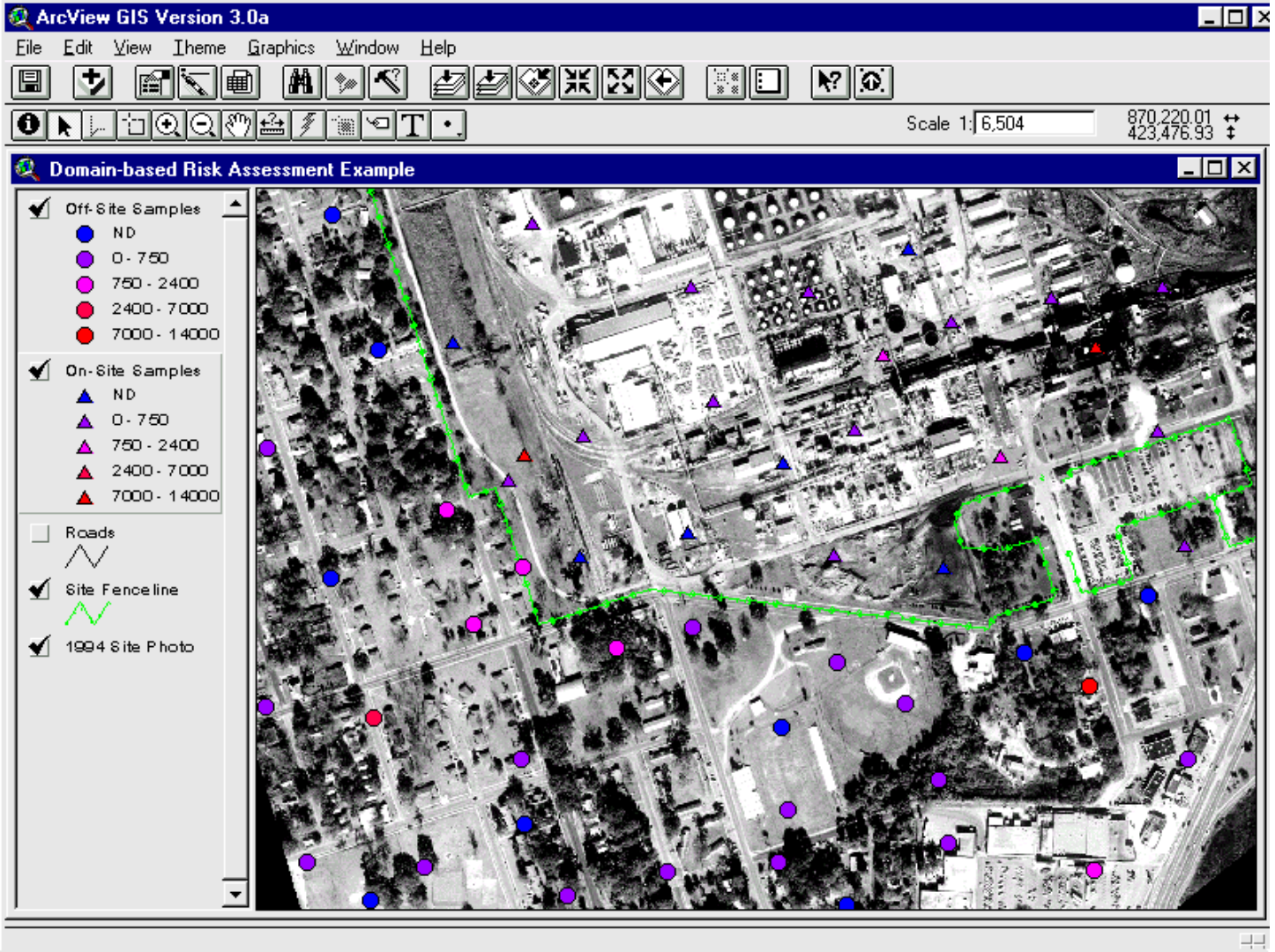
Land Use Guidance

EPA Guidance: *OSWER Directive #9355.7-04 Land Use in the CERCLA Remedy Selection Process*

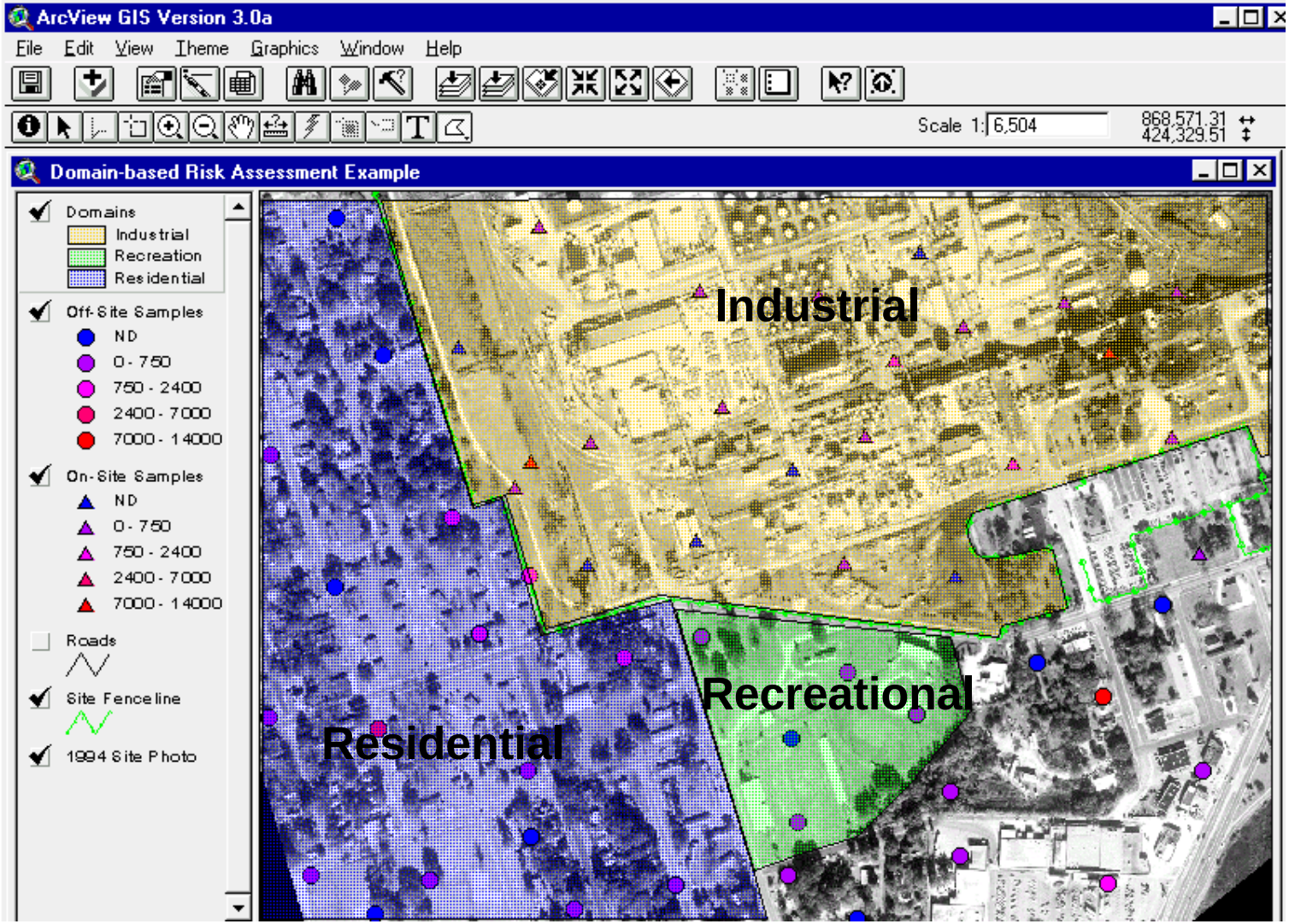
Risk assessment should be based on reasonable future use of the site-residential use need not be evaluated if not reasonable



Exposure Domain Example



Exposure Domain Example



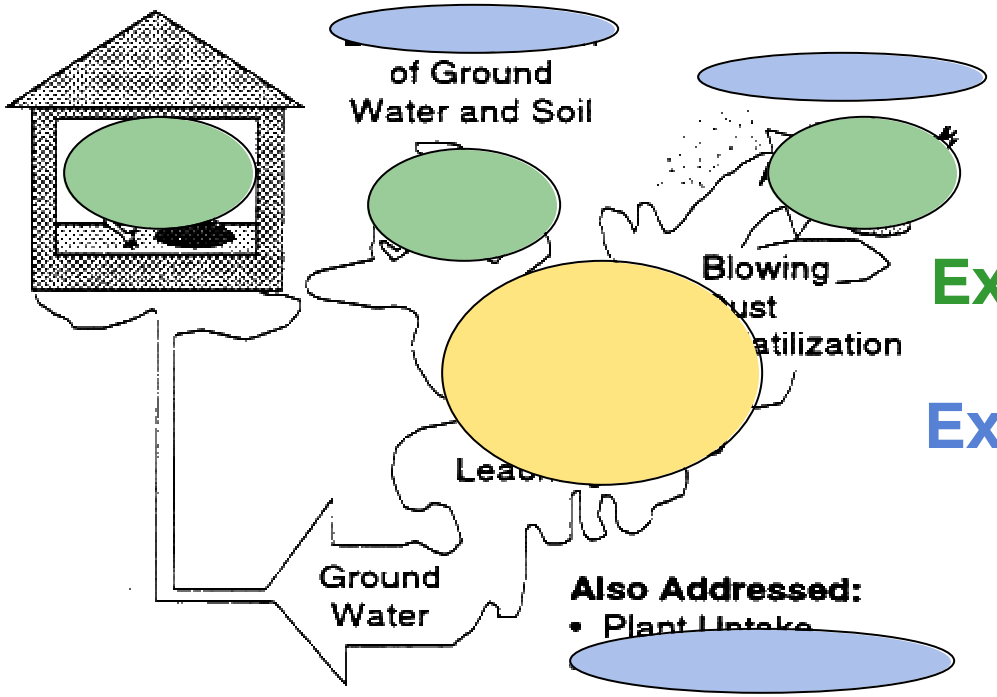
Exposure Domain

Identify Receptors

- Who will come in contact with constituents?
  - Land use
  - Activities
  - Climate
  - Age groups
  - Sensitive subpopulations

Complete Exposure Pathways

- **Source** or chemical release from a source
- **Exposure point** where contact can occur
- **Exposure route** for contact to occur



Source

Exposure point

Exposure route

Exposure Pathways

Be Reasonable!!!

Risk Assessment should quantify majority of risk and should focus on *significant* exposure pathways and constituents

Exposure Pathways

- Residential
  - Incidental soil ingestion
  - Dermal soil contact
  - Soil particulate inhalation
  - Inhalation of volatiles
  - Groundwater ingestion
  - Dermal groundwater contact
  - Volatile inhalation while showering

Exposure Pathways

- **Commercial and Industrial**
  - Incidental soil ingestion
  - Dermal soil contact
  - Soil particulate inhalation
  - Inhalation of volatiles from soil
  - Ingestion of groundwater

maintenance, utility and construction workers face possible dermal exposure to groundwater and volatile inhalation from groundwater

Eliminating Complete Exposure Pathways

Should retain all complete exposure pathways unless sound justification to eliminate.

Example

Exposure from pathway is much less than that from another pathway involving the same medium and exposure point

Don’t quantitatively evaluate trespassers if you are doing residential over same exposure domain

Eliminating Complete Exposure Pathways

- Potential magnitude of exposure from pathway is low

- Probability of exposure very low and the risks associated with occurrence are not high (no catastrophic effects if exposure does occur)

General Equation

$$I = \frac{C \times CR \times EF \times ED}{BW} \times \frac{1}{AT}$$

Intake = Chemical conc. *x* contact rate *x* exposure frequency *x* duration / body weight *x* averaging time

- chemical related variable
- exposed population variable
- assessment-determined variable

Default Exposure Parameters

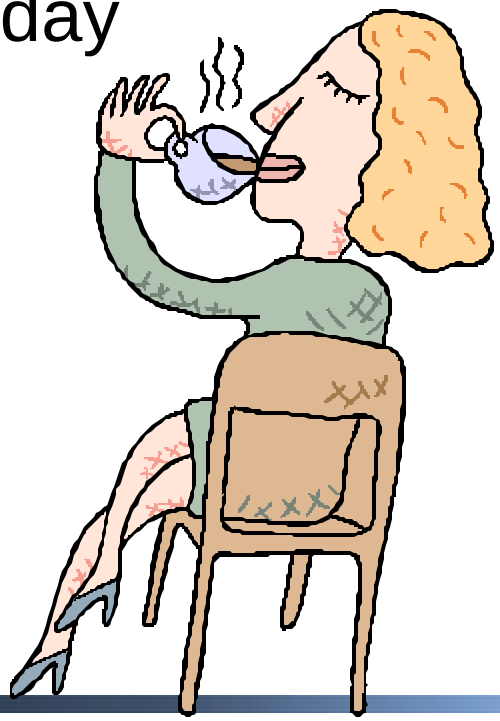
CR = Contact Rate (residential)

Drinking water ingestion (8 glasses of H_2O)

- Adult 90th percentile -- 2 liters/day
- Adult average -- 1.4 liters/day
- Children -- 1.0 liter/day

Incidental soil ingestion

- Adult -- 100 mg/day
- Children -- 200 mg/day



Default Exposure Parameters

EF = Exposure Frequency

Drinking water & incidental soil ingestion(residential)

365 days/year = maximum

350 days/year = upper bound (2 week vacation)

Drinking water & incidental soil ingestion (industrial)

250 days/year (5 days/week for 50 weeks)

Default Exposure Parameters

ED = Exposure Duration

Residential

- 70 years: (lifetime) maximum
- 30 years: national upper bound 90th percentile
- 9 years: national median 50th percentile

Industrial

- 25 years: national upper bound 90th percentile
- 1-60 years: occupation dependent

Default Exposure Parameters

BW = Body Weight

70 kg: average adult (7 - 31 years)

15 kg: average child (1 - 6 years)

AT = Averaging Time

Non-carcinogens: AT = ED x 365

Carcinogens = 70 years (lifetime)

Site-Specific Exposure Parameters

Information on exposed population and site-related activities demonstrate that default values do not adequately describe potential exposures.

Example

North Dakota -- snow cover would reduce days of exposure to soil
Florida -- drinking water ingestion may be higher

Site-Specific Exposure Parameters

- Recreational Land Use
  - observation
  - surveys
  - interviews
- Industrial Land Use
  - job descriptions
  - interviews

Exposure Parameter Sources

- RAGS Part A
- RAGS Part B
- RAGS Supplemental Guidance -- Standard Default Exposure Factors
- Exposure Factors Handbook
- Dermal Assessment Guidance (RAGS Part E)
- State and/or local surveys (MI state parks)
- Literature Search

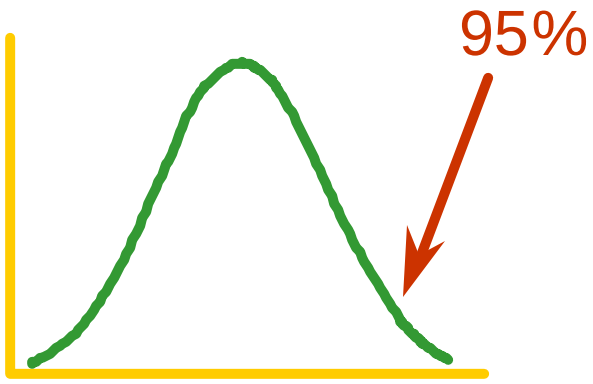
Other Guidance

New guidance with significant potential impact

- Vapor Intrusion
  - Evaluating the Vapor Intrusion into Indoor Air
    November 2002

Exposure Assumptions

Intake variables for a given pathway should be selected so that the ***combination*** of all intake variables results in an estimate of the reasonable maximum exposure (RME) for that pathway.



RAGS Part A

Example Table

Exposure Route	Parameter Code	Parameter Definition	Units	RME Value	RME Rationale/ Reference
Adult Recreational: Soil					
Ingestion	CS	Chemical Concentration in Soil	mg/kg	(1)	(1)
	IR	Ingestion Rate of Soil	mg soil/day	50	EPA, 1991
	EF	Exposure Frequency	days/year	40	(2)(3a)
	ED	Exposure Duration	years	25	EPA, 1991
	ABS	Absorption Factor	--	1	(4)
	CF1	Conversion Factor	kg/mg	1.00E-06	--
	BW	Body Weight	kg	70	EPA, 1991
	AT-C	Averaging Time (Cancer)	days	25,550	EPA, 1989
	AT-N	Averaging Time (Non-Cancer)	days	9,125	EPA, 1989
	FI	Fraction Ingested	--	1.00	(2)
Worst Case Scenario					
Parameter	**Slope Factor (SF)**	**Reference Dose (RfDo)**	Reference		
Arsenic	1.50E+00	3.00E-04	ii	ii=IRIS	
Benzo(a)anthracene	7.30E-01		n	h=HEAST	
Benzo(a)pyrene	7.30E+00		ii	n=NCEA	
TEQ	1.50E+05		h		
Aluminum		1.00E+00	n		
Anitmony		4.00E-04	ii		
Barium		7.00E-02	ii		
Cadmium		5.00E-04	ii		
Cyanide		2.00E-02	ii		
Iron		3.00E-01	ii		
Lead					
Manganese		2.40E-02			
Mercury					
Selenium		5.00E-03	ii		
Silver		5.00E-03	ii		
Vanadium		7.00E-03	h		
Zinc		3.00E-01	ii		
Pyrene		3.00E-02	ii		
Phenanthrene					
Fluoranthene		4.00E-02	ii		
Naphthalene		2.00E-02	ii		

Risk Characterization

PURPOSE

To combine the results of the *Exposure Assessment* and *Toxicity Assessment* to determine the likelihood that health effects could occur in people who came in contact with substances at a site.

for:

- Carcinogens
- Non-Carcinogens

Risk Characterization

Combines information on toxicity and exposure

Determines probability of cancer for carcinogens

Calculates ratio of daily intake to an acceptable daily intake value for non-carcinogens

Additivity

Each Exposure Pathway

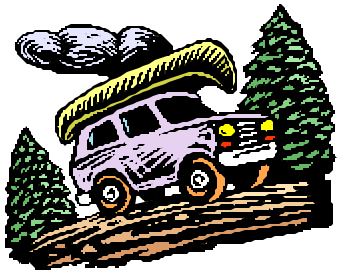
- Add risks of all carcinogenic compounds
- Add hazards of all noncarcinogenic compounds

All Exposure Pathways

- Add risks of all carcinogenic compounds across all exposure pathways
- Add risks of all noncarcinogenic compounds across all exposure pathways

Guidance on Combining Pathways

"For real world situations in which contaminant concentrations vary over time and space, the same individual may or may not experience the RME for more than one pathway over the same period of time."



RAGS Part A

Guidance on Combining Pathways

"Only if you can explain why the key RME assumptions for more than one pathway apply to the same individual or subpopulation should the RME risks for more than one pathway be combined."

RAGS Section 8.3.1 (Pg. 8-16)

May be more appropriate to combine **RME** for one pathway and more **typical exposure parameter values** for another pathway

Carcinogenic Effects

Express using only one significant figure:

~~3.21×10^{-5}~~

3×10^{-5}

TABLE 9.1 RME
SUMMARY OF RECEPTOR RISKS AND HAZARDS FOR COPCs
REASONABLE MAXIMUM EXPOSURE
Washington Navy Yard - Site 16

Scenario Timeframe: Future
Receptor Population: Construction Worker
Receptor Age: Adult

Medium	Exposure Medium	Exposure Point	Chemical	Carcinogenic Risk				Chemical	Non-Carcinogenic Hazard Quotient				
				Ingestion	Inhalation	Dermal Absorption	Exposure Routes Total		Primary Target Organ	Ingestion	Inhalation	Dermal Absorption	Exposure Routes Total
Groundwater	Groundwater	Columbia Aquifer - Water in Excavation Pit	Benzene	--	--	1.3E-07	1.3E-07	Benzene	Liver	--	--	1.0E-01	1.0E-01
			Bromodichloromethane	--	--	2.6E-11	2.6E-11	Bromodichloromethane	Kidney	--	--	1.4E-06	1.4E-06
			Chloroform	--	--	3.7E-12	3.7E-12	Chloroform	Liver	--	--	4.2E-06	4.2E-06
			Dibromochloromethane	--	--	2.9E-04	2.9E-04	Dibromochloromethane	Liver	--	--	1.2E+01	1.2E+01
			beta-BHC	--	--	4.6E-03	4.6E-03	Dibenzofuran	Kidney	--	--	1.7E+04	1.7E+04
			delta-BHC	--	--	1.3E-02	1.3E-02	Aluminum	CNS	--	--	1.7E-02	1.7E-02
			Total Dioxins**	--	--	1.0E-02	1.0E-02	Antimony	Blood	--	--	9.6E-03	9.6E-03
			Arsenic	--	--	7.7E-08	7.7E-08	Arsenic	Skin	--	--	1.2E-02	1.2E-02
								Barium	Cardiovascular	--	--	1.1E-03	1.1E-03
								Cadmium	Kidney	--	--	2.1E-01	2.1E-01
								Chromium	NOAEL	--	--	5.0E-02	5.0E-02
								Iron	GI	--	--	2.5E-01	2.5E-01
								Manganese	CNS	--	--	2.7E-02	2.7E-02
								Thallium	Liver & Blood	--	--	6.2E-03	6.2E-03
								Vanadium	NOAEL	--	--	1.7E-01	1.7E-01
			(Total)	--	--	2.8E-02	2.8E-02	(Total)		--	--	1.7E+04	1.7E+04
	Air	Columbia Aquifer - Volatilization from Water in Excavation Pit	Benzene	--	2.3E-07	--	2.3E-07	Benzene	Liver	--	3.3E-02	--	3.3E-02
			Chloroform	--	1.8E-10	--	1.8E-10	Chloroform	Liver	--	1.8E-04	--	1.8E-04
			(Total)	--	2.4E-07	--	2.4E-07	(Total)		--	3.4E-02	--	3.4E-02
				Total Risk Across Groundwater			2.8E-02		Total Hazard Index Across Groundwater				1.7E+04

Don't overstate the precision -
the uncertainty could span orders of magnitude

Uncertainty Analysis

Uncertainty is involved in all phases

- Data collection and evaluation
- Exposure Assessment
- Toxicity Assessment
- Risk Characterization

Uncertainty Analysis

Estimates of risk are not fully probabilistic

They are conditional estimates given a number of assumptions about exposure and toxicity (risk given a particular future land use)

Need to fully specify assumptions and uncertainties inherent in the risk assessment to place risk estimates in proper perspective

Sources of Uncertainty

Uncertainty about numerical results is generally large

Range of at least one order of magnitude

Uncertainty and Variability

Uncertainty - *lack of knowledge*

- concentration of constituent
- local fish consumption

More data will decrease uncertainty

Variability - *true heterogeneity*

- adult body weights
- drinking water intake in young children

More data will not decrease variability

Summary

Baseline Risk Assessment

- Four Steps
  - Data collection and evaluation
  - Toxicity assessment
  - Exposure assessment
  - Risk characterization
- Reflects reasonable exposure pathways/combinations
- Uncertainty analysis
  - Perspective on risk estimates
  - Many sources of uncertainty


PHILIP MORRIS
WHAT DO YOU DO WHEN YOU RUN OUT OF HUMANS?
START USING LAWYERS
THESE STUDIES ARE INCONCLUSIVE—SO FAR WE'VE ONLY SUCCEEDED IN GIVING CANCER AND HEART DISEASE TO LABORATORY HUMANS.